Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparing the effectiveness of Tofacitinib (Alpamont) and Adalimumab (CinnoRa) on nail lesions' treatment in patients with Psoriatic Arthritis: A clinical trial study

Protocol summary

Study aim

To evaluate the efficacy and safety of tofacitinib versus adalimumab in treating nail, joint, and skin involvement in psoriatic arthritis patients.

Design

Randomized, parallel-group, open-label Phase 3 clinical trial involving 70 psoriatic arthritis patients with nail involvement. Participants will be randomly assigned (1:1) using block randomization with variable block sizes (4, 6, 8).

Settings and conduct

The study is conducted at the Rheumatology Clinic of Ahvaz Jundishapur University of Medical Sciences. Patients are randomly assigned to receive tofacitinib (5 mg tablets, every two weeks) or adalimumab (40 mg injections, every two weeks) for 12 weeks. Clinical assessments are performed at weeks 0, 8, and 12 using the NAPSI and Lesion Quadrant indices. Blinding is not implemented.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Diagnosis of psoriatic arthritis per CASPAR criteria confirmed by a rheumatologist and a dermatologist; nail involvement; prior use of disease-modifying antirheumatic drugs (DMARDs). Exclusion Criteria: History of hypersensitivity to study drugs; severe infections or concurrent malignancies; pregnancy or breastfeeding; other rheumatologic diseases; fungal or infectious nail diseases; history of deep vein thrombosis (DVT); cardiovascular diseases; smoking.

Intervention groups

Group 1 (Tofacitinib): 5 mg tofacitinib tablets (Aburaihan Pharmaceutical Company), orally every two weeks for 12 weeks. Group 2 (Adalimumab): 40 mg adalimumab injections (SinaGen Pharmaceutical Company), subcutaneously every two weeks for 12 weeks.

Main outcome variables

Primary outcomes: Changes in Nail Psoriasis Severity Index (NAPSI) and Lesion Quadrant Index from baseline to week 12.

General information

Reason for update

Please be informed that the outcome assessment time points have been revised from baseline, week 4, week 8, and week 12 to baseline, week 8, and week 12. In addition, the sample size has been revised to 70 participants. All changes were made in consultation with a biostatistics specialist; therefore, the clinical trial registration has been updated accordingly.

Acronym

IRCT registration information

IRCT registration number: **IRCT20250503065587N1**
Registration date: **2025-05-13, 1404/02/23**
Registration timing: **prospective**

Last update: **2025-12-25, 1404/10/04**
Update count: **1**

Registration date

2025-05-13, 1404/02/23

Registrant information

Name

Aliakbar Gorjipour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3311 6515

Email address

aligorji3335@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2025-05-22, 1404/03/01
Expected recruitment end date
2025-10-22, 1404/07/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the effectiveness of Tofacitinib (Alpamont) and Adalimumab (CinnoRa) on nail lesions' treatment in patients with Psoriatic Arthritis: A clinical trial study

Public title
Comparison of the effectiveness of tofacitinib and adalimumab in treating nail involvement in patients with psoriatic arthritis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of psoriatic arthritis based on CASPAR criteria Presence of nail involvement confirmed by rheumatologist and dermatologist History of using DMARDs for controlling psoriatic arthritis Age over 18 years Ability to provide written informed consent
Exclusion criteria:
History of hypersensitivity to the medications used in the study Presence of severe infections or concurrent malignancies Pregnancy or breastfeeding Concurrent presence of other rheumatologic diseases History of fungal or infectious nail diseases History of deep vein thrombosis (DVT) History of cardiovascular diseases Being a smoker Use of medications that may interfere with the study drugs Participation in other clinical trials within the past 30 days Presence of severe psychiatric disorders affecting compliance with the study protocol
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
- Randomization Method: Randomized block design with sizes of 4, 6, and 8. - Randomization Tool and Block Construction: The Sealed Envelope simple randomisation service website. - Randomization Unit: Individual participants. - No Stratification Layers: There are no stratification layers in the randomization process. - Unique Codes: After generating the random sequence using the aforementioned online software, a unique code is assigned to each individual. The list of random sequences and unique codes is maintained by the principal investigator. Participants are enrolled in the study in the order determined by the generated random sequence. - To ensure allocation concealment, sealed envelopes will be used.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Biomedical Research Ethics Committee of Ahvaz Jundishapur University of Medical Sciences
Street address
Golestan Highway
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Approval date
2025-05-03, 1404/02/13
Ethics committee reference number
IR.AJUMS.REC.1404.087

Health conditions studied

1

Description of health condition studied
Nail Psoriasis
ICD-10 code
L40.9
ICD-10 code description
Psoriasis, unspecified

Primary outcomes

1

Description
Nail Psoriasis Severity Index (NAPSI) score
Timepoint
At baseline (week 0) and at weeks 8, and 12 after treatment initiation.
Method of measurement
Researcher-Made Checklist

Secondary outcomes

1

Description
Incidence of treatment-related adverse events associated with tofacitinib or adalimumab in patients with psoriatic arthritis during the 12 weeks following treatment initiation.
Timepoint
Baseline (prior to initiation of treatment), Week Week 8 after treatment initiation, and Week 12 (end of treatment period).
Method of measurement
Researcher-Made Checklist

Intervention groups

1

Description
Intervention group: First Group (Tofacitinib): 5 mg oral tofacitinib tablets (brand name "Urositra," manufactured by Sobhan Darou Pharmaceutical Co., Iran) administered orally once every two weeks for a duration of 12 weeks, under treatment and evaluation.
Category
Treatment - Drugs

2

Description
Intervention Group: Group 2 (Adalimumab): 40 mg subcutaneous injection of adalimumab (brand name "Humira" by AbbVie) is administered every two weeks for a duration of 12 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Golestan Educational and medical Center
Full name of responsible person
Armin Jahangiri babadi
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Abdollah Rafiei
Street address
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Aliakbar Gorjipour
Position
Resident
Latest degree
Specialist
Other areas of specialty/work
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Position

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Latest degree

Specialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Upon completion of the study, the following documents will be made publicly available: study protocol, statistical analysis plan, clinical study report, analysis codes, and data dictionary. Participant data will be maintained in an anonymized format and may be shared with qualified researchers upon approval from the Ethics Committee of Ahvaz Jundishapur University of Medical Sciences, in compliance with ethical research guidelines. Regarding individual participant data, only information related to the primary outcome of the study will be accessible. All data will be shared after de-identification and in adherence to ethical research principles and applicable regulations.

When the data will become available and for how long

Six Months After Publication of the Article

To whom data/document is available

Access will be granted to academic researchers and investigators actively engaged in related fields.

Under which criteria data/document could be used

Data and documents are available solely for scientific research purposes and not for commercial use. Access requires a formal request, approval from the Ethics Committee of Ahvaz Jundishapur University of Medical Sciences, and a signed data use agreement.

From where data/document is obtainable

Researchers from the faculty, students, medical assistants, and investigators can access data by presenting an introduction letter from their respective university or institution and contacting the Research and Technology Department of Jundishapur University of Medical Sciences in Ahvaz. They must submit a proposal and obtain an ethical code from the university's ethics committee. Applicants seeking access to the data can contact Dr. Abdollah Rafiei via email at rafiei-a@ajums.ac.ir, who serves as the Vice Chancellor for Research and Technology at Jundishapur University of Medical Sciences, and Dr. Elham Rajaei, the project manager, at rajaei-e@ajums.ac.ir.

What processes are involved for a request to access data/document

Researchers may submit requests through formal correspondence with the Research and Technology Department. Access is contingent upon obtaining ethical

approval from the university's Ethics Committee.

Comments